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(12) # EUROPEAN PATENT SPECIFICATION

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(54) **Ion beam Sputter-etched ventricular catheter for hydrocephalus shunt.**

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DE-A-2 813 750
FR-A-2 309 242
FR-A-2 329 295
US-A-2 267 714
US-A-2 267 752
US-A-3 669 116

(73) Proprietor: **NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**
NASA Headquarters
Washington, D.C. 20546 (US)

(72) Inventor: **Banks, Bruce Alan**
26931 Eastwood Lane
Olmsted Township Ohio 94138 (US)

(74) Representative: **Bühling, Gerhard, Dipl.-Chem. et al**
Patentanwaltsbüro Tiedtke-Bühling-Kinne Grupe-Pellmann-Grams-Struif Bavariaring 4
D-8000 München 2 (DE)

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Description

This invention is directed to an improved cerebrospinal fluid shunt in the form of a ventricular catheter for controlling the condition of hydrocephalus by relieving the excessive cerebrospinal fluid pressure. The invention is further concerned with an improved method for fabricating the catheter.

The obstruction of cerebrospinal fluid flow pathways or its inadequate absorption via the arachnoid villi into the venous blood of the brain results in hydrocephalus. Surgical correction involves pressure controlled shunting of the cerebrospinal fluid. Typically, a perforated silicon rubber catheter is implanted in one of the lateral ventricles of the brain with its perforated tip located near the frontal horn. The cerebrospinal fluid passes through a pressure regulating valve and is then typically shunted to the right atrium of the heart or the peritoneal cavity.

The shunt will fail to function if the inlet ventricular catheter apertures become blocked. Shunt flow failure will also occur if the ventricle collapses due to improper valve function causing over drainage.

Heretofore, previously designed ventricular catheters have been found deficient as a result of high incidence of inlet blockage caused by the ingrowth of the choroid plexas, ventrical collapse over the catheter orifices, or hemorrhage, cellular, and fibrin debris. Multiple surgical revisions during the first several years after birth is common because of inlet blockage of the catheters.

Various geometry ventricular catheters have been proposed in which the inlet orifices are hidden or covered by complicated structures. The hidden inlet type geometries have not resulted in a decreased probability of blockage.

US—A—4,182,343 discloses a double ventricular drain tube having a double cavity. A rubber outer tube has one end which is sealed with the other end being open. This outer tube encloses a rubber inner tube that is shorter than the outer tube. One end of the inner tube is fixed to the inner wall of the sealed end of the outer tube and the other end of the inner tube is open. This inner tube may or may not be fixed to the inner wall of the outer tube. The outer tube and the inner tube, respectively, have a plurality of holes passing through their respective side walls. The holes through the outer tube side walls are positioned in such a manner so that they do not align with the holes in the side walls of the inner tube.

US—A—3,595,241 discloses a medicosurgical tube having a swab member positioned inside the tube so constructed or arranged that it may be pulled through the tube and out the proximal end. In such a catheter, the lumen is positively protected throughout the tube length against the possibility of blood clots or other matter preventing liquid flow through the tube following the tube insertion procedure.

US—A—3,753,439 and US—A—3,823,720 disclose several types of surgical drains. These drains rely on relatively large holes in the tube wall, and a padding or net is utilized to prevent entry of material into the holes. None of the prior art patents discloses a catheter which would be suitable for insertion into the human brain.

FR—A—23 09 242 discloses a catheter according to the classifying portion of claim 1. This catheter is used for local treatment of human and animal organism by the injection of specific substances, or to perform, particularly by aspiration, a sampling of any local area of a tissue.

The microtubular members of the catheter have a hard and firm tip at that end inserted in the tissue and the diameter of the microtubular member is approximately within the range of from 1 to 3 mm. The long and continuously firm tip of the microtubular members and the relatively great diameter of the microtubular members may lead to tissue injury when used as ventricular catheter, which may lead to an occlusion of the minute openings.

DE—A—28 13 750 relates to a tubular flexible medical instrument for insertion in cavities of the body consisting of a sintered polytetrafluorethylene tube comprising one firm area or a plurality of firm areas and one porous area or a plurality of porous areas. These tubular instruments may be used as infusion cannulas having a rigid tip of the tube. The known catheter tubules have an approximate diameter of 2.5 mm and an interior diameter of 1.5 mm.

US—A—22 67 714 and US—A—22 67 752 relate to the manufacture of filters, the pores of which are produced by corpuscular beams. However, these printed publications do not mention catheters.

Accordingly, the object underlying the present invention consists in improving the catheter described in the classifying portion of claim 1 in such a way that the the tendency for the catheter to draw in and trap debris of tissue is reduced, so that the excessive cerebrospinal fluid pressure can be relieved without risk of fluid blockage. A further object consists in a method of making such a catheter.

The objects of the invention are achieved by the characterizing portion of claim 1 and claim 9 respectively. Preferred embodiments are described in the subclaims.

The ventricular catheter of the present invention comprises a multiplicity of inlet microtubules. Each microtubule has both a large opening at its inlet end and a multiplicity of ion beam sputtered microscopic openings along its lateral surfaces.

The microtubules are perforated by a ion beam sputter etch technique. The holes are etched in each microtubule by directing an ion beam through an electro formed metal mesh mask producing perforations having diameters ranging from 14 µm to about 150 µm.

This combination of a multiplicity of microtubes, the numerous small perforations provided in the lateral surfaces of the tubes, and the hydra-like distribution of the tubes provide a

reliable catheter for shunting cerebrospinal fluid from the cerebral ventricles to selected areas of the body.

The invention will be more fully apparent from the following detailed description when read in conjunction with the accompanying drawings wherein

FIG. 1 is an enlarged view of a ventricular catheter constructed in accordance with the present invention,

FIG. 2 is a schematic view showing apparatus for perforating the walls of the microtubules utilized in the catheter shown in FIG. 1.

FIG. 3 is an enlarged sectional view taken along the lines 3—3 in FIG. 2,

FIG. 4 is a scanning electron photomicrograph showing the outside surface of a sputter perforated microtubule.

FIG. 5 is a scanning electron photomicrograph showing a sputter perforated microtubule in section, and

FIG. 6 is a schematic view showing the direct shunting of cerebrospinal fluid from a lateral ventricle to the subarachnoid space using sputter perforated microtubules.

Referring now to the drawing there is shown in FIG. 1 a ventricular catheter 10 constructed in accordance with the present invention. Each catheter 10 comprises a plurality of pliable microtubules 12. A bundle of the microtubules 12 may be covered by a tubular sheath 14 which is connected to a conventional valved shunting system.

The microtubules 12 are of a fluoropolymer material and can be varied in number, diameter, wall thickness, length and material. Typical fluoropolymers that are satisfactory for the microtubules 12 are polytetrafluoroethylene and fluoroethylene propylene. Living cells of the human body tend not to adhere to such materials, and no major anchorage problem results.

Each microtubule 12 has an inlet end 16 which is preferably open and is of a larger diameter than each of the multiplicity of ion beam sputtered microscopic perforations 18 along a relatively long extent of the lateral surfaces as shown in greater detail in FIGS. 4 and 5. It is further contemplated that the inlet end 16 may be closed in certain embodiments.

The tubular sheath 14 is preferably of a silicone rubber tubing of small diameter to minimize the penetration thereby reducing the danger of infection. Silicon tubing having an outer diameter of about .015 m has been satisfactory. The type of transition from the fluorocarbon bundle to the silicone rubber tubing can be varied in geometry.

Preselected areas of the microtubules 12 are perforated by exposing them to an ion beam 20 from a suitable source 22 as shown in FIG. 2. The ion beam 20 is between 300 eV and 500 eV with a density sufficient to perforate the microtubules 12 at a predetermined exposure time as shown in FIGS. 4 and 5.

The argon ion beam may be from an electron bombardment ion source 22 of the type developed from electric propulsion technology. Such an ion source is described in "Advances in Electronics and Electron Physics" by H. R. Kaufman, Vol. 36, pages 265 to 373, 1974.

Beam extraction may be accomplished by a dished, two grid ion optics system. Such a system is described in AIAA Paper No. 76-1017 entitled "A 30 cm Diameter Argon Ion Source". Neutralization of the ion beam may be achieved by secondary electrons released by ion bombardment of the walls of a vacuum facility (not shown) which houses the ion source 22. This vacuum facility is sufficiently large to minimize back sputtered facility material from contaminating the material being ion beam etched. The vacuum facility normally is maintained at a pressure of 5.3×10^{-5} mbar (4×10^{-5} torr) during the operation of the ion source 22.

Microtubules 12 are mounted around the outer peripheral surface of a cylindrical mandrel 24 mounted for rotation about its normal axis downstream from the ion source 22. A suitable shield 26 is positioned between the source 22 and the mandrel 24 in close proximity with the mandrel. The ion beam 20 passes through the shield 26 in a manner well known in the art.

An electroformed screen 28 of extremely fine mesh is held in tension around the outermost surface edges of the microtubules 12 on the mandrel 24 as shown in FIG. 3. Argon ions from the beam 20 pass through the screen 28 to form a pattern of perforations 18 as shown in FIG. 4. More particularly, the electroformed metal mesh screen 28 functions as a mask to produce the desired apertures through the walls in the microtubules 12. These apertures 18 are microscopic in size, having a diameter between about 14 µm and 150 µm. The portion of the ion beam 20 passing through the shield 26 is shown in FIG. 3 and is substantially uniform in density throughout its entire width.

The utilization of sputter etching to perforate the inlet ventricular catheter microtubules 12 facilitates the fabrication of catheters having two orders of magnitude increase in aperture density over that of conventional catheters shown in the prior art. This is evident because approximately 1100 apertures for each 20 µm in diameter can be placed along a 1 cm length of microtubule.

The catheter 10 is comprised of a bundle of one or more microtubules 12, each being only about 0.44 mm in diameter. The resulting large number of inlet apertures reduces the tendency for the shunt to draw in and trap debris or tissue which would then cause flow obstruction.

The catheter 10 can be used to drain cerebrospinal fluid from one of the lateral ventricles through a conventional valved shunting system to either the heart or the peritoneal cavity. The catheter also can be used for direct shunting of cerebrospinal fluid from a lateral ventricle 30 to selected areas of the human body using individual microtubules 12 as shown in FIG. 6. This lateral ventricle is in substantial juxtaposition with the third ventricle 32 which is positioned above the fourth ventricle 34.

The microtubules 12 extend from the lateral ventricle up through the pia mater to the subarachnoid space 38. This space is between the pia mater 36 and the arachnoid 40 which is positioned inwardly from the dura mater 42. The inlet ends 16 of the microtubules 12 extend into the lateral ventricle 30 in a hydra-like fashion. Likewise, the outermost or discharge end of the microtubules 12 extend hydra-like in the subarachnoid space 38.

It will be appreciated that the positioning of the catheter 10 as shown in FIG. 6 does not require any pressure regulating valves. Such valves are used with conventional catheters that return the cerebrospinal fluid to the heart or peritoneal cavity. Also, this procedure returns the cerebrospinal fluid to its site of normal absorption in the subarachnoid space 38.

The large number of inlet apertures 18 formed by the perforations reduces the tendency for a shunt to draw in and trap debris or tissue which would then flow or cause flow obstruction. Also, this combination of extremely small apertures in the lateral surfaces of the microtubules together with the fluoropolymer material of the microtubules reduces the mechanical attachment of tissue and aids revisions if needed. The small diameter of the perforations 18 reduces the probability of cerebrospinal fluid flow blockage caused by localized collapse of the ventricle.

It is contemplated that both the material and the geometry of the sputter mask mesh 28 can be varied. This, in turn, changes the positioning as well as the configuration of the perforations 18 in the microtubules 12. It is also contemplated that while the microtubules 12 are shown mounted on a mandrel 24 in a substantial parallel juxtaposition, as shown in both FIGS. 2 and 3, other mounting arrangements may be relied on. More particularly, the microtubules 12 may be wrapped on the mandrel 24 in a spiral mounting. It is further contemplated that the microtubules 12 shown in FIG. 3 may be twisted and held in a twisted position during ion sputtering. Subsequent to the perforations 18 being formed the twisting forces are removed so that the perforations then have a general spiral configuration about the walls of the microtubules 12.

Claims

1. A catheter comprising a plurality of microtubular members (12), each of said microtubular members (12) having a plurality of perforations (18) in a portion of the walls thereof adjacent to at least one end of said member (12), characterized in that said catheter is a ventricular catheter for controlling the condition of hydrocephalus by relieving the excessive cerebrospinal fluid pressure, in that said one end has an opening (16) therin that is substantially greater than each of said perforations (18) and in that the perforations (18) are ion beam sputtered microscopic perforations.

2. A catheter as claimed in claim 1 wherein the microtubular members (12) are of a fluoropolymer material.

3. A catheter as claimed in claim 2 wherein the microtubular members (12) are of a fluoropolymer material selected from the group consisting essentially of polytetrafluoroethylene and fluoroethylene propylene.

4. A catheter as claimed in claim 1 including a tubular sheath member (14) for enclosing said microtubular members (12) with said perforated portions of said microtubular members (12) extending from one end of said sheath (14).

5. A catheter as claimed in claim 4 wherein the tubular sheath member (14) is of a silicone rubber material.

6. A catheter as claimed in claim 5 wherein the tubular sheath member (14) has a diameter of about 0.015 m.

7. A catheter as claimed in claim 6, wherein the microtubular members (12) have diameters of about 0.44 mm.

8. A catheter as claimed in claim 7 wherein the perforations (18) in the microtubular members (12) have diameters between about 14 µm and 150 µm.

9. A method of making a catheter according to claims 1 to 8 characterized by

covering a plurality of microtubular members (12) with a mask (28) having a plurality of microscopic openings therein,

placing said covered microtubular members (12) in a vacuum environment, and

exposing said mask (28) to a beam of ions whereby perforations (18) are produced in said microtubular members (12).

10. A method of making a catheter as claimed in claim 9 characterized by enclosing a plurality of said perforated microtubular members (12) in a tubular sheath (14).

Patentansprüche

1. Katheter mit einer Vielzahl von Mikroröhren (12), wobei jede erwähnten Mikroröhren (12) in einem Bereich ihrer Wand, der mindestens an ein Ende der erwähnten Mikroröhre (12) angrenzt, eine Vielzahl von Löchern (18) aufweist, dadurch gekennzeichnet, daß der erwähnte Katheter ein Ventrikel-Katheter für die Beherrschung des Hydrozephaluszustandes durch Verminderung des übermäßigen Druckes der zerebrospinalen Flüssigkeit ist, daß sich in dem erwähnten einen Ende eine Öffnung (16) befindet, die wesentlich größer ist als jedes der erwähnten Löcher (18), und daß die Löcher (18) mikroskopisch kleine Löcher sind, die durch Zerstäubung mit einem Ionenstrahl erzeugt wurden.

2. Katheter nach Anspruch 1, bei dem die Mikroröhren (12) aus einem Fluorpolymermaterial bestehen.

3. Katheter nach Anspruch 2, bei dem die Mikroröhren (12) aus einem Fluorpolymermaterial bestehen, das aus der Gruppe ausgewählt ist, die im wesentlichen aus Polytetrafluorethylen und Fluorethylenpropylen besteht.

4. Katheter nach Anspruch 1, der eine röhrenförmige Umhüllung (14) zum Einschließen der erwähnten Mikroröhren (12) enthält, wobei sich die erwähnten, Löcher aufweisenden Bereiche der erwähnten Mikroröhren (12) von einem Ende der erwähnten Umhüllung (14) aus erstrecken.

5. Katheter nach Anspruch 4, bei dem die röhrenförmige Umhüllung (14) aus einem Siliconkautschukmaterial besteht.

6. Katheter nach Anspruch 5, bei dem die röhrenförmige Umhüllung (14) einen Durchmesser von etwa 0,015 m hat.

7. Katheter nach Anspruch 6, bei dem die Mikroröhren (12) Durchmesser von etwa 0,44 mm haben.

8. Katheter nach Anspruch 7, bei dem die Löcher (18) in den Mikroröhren (12) Durchmesser zwischen etwa 14 µm und 150 µm haben.

9. Verfahren zur Herstellung eines Katheters nach Ansprüchen 1 bis 8, dadurch gekennzeichnet, daß

eine Vielzahl von Mikroröhren (12) mit einer ske (28), in der sich eine Vielzahl mikroskopisch kleiner Öffnungen befindet, abgedeckt wird,

die erwähnten abgedeckten Mikroröhren (12) in eine Vakuumumgebung gebracht werden und

die erwähnte Maske (28) einem Ionenstrahl ausgesetzt wird, wodurch in den erwähnten Mikroröhren (12) Löcher (18) erzeugt werden.

10. Verfahren zur Herstellung eines Katheters nach Anspruch 9, dadurch gekennzeichnet, daß eine Vielzahl der erwähnten, Löcher aufweisenden Mikroröhren (12) in eine röhrenförmige Umhüllung (14) eingeschlossen wird.

Revendications

1. Catheter comprenant une multiplicité de pièces microtubulaires (12) chacune de ces pièces microtubulaires (12) ayant une multiplicité de perforations (18) sur une portion des parois de ces pièces, adjacentes à moins une extrémité de la pièce (12), caractérisé en ce que le catheter est ' catheter ventriculaire pour contrôler les condi-..ons de l'hydrocéphalie par réduction de la pression excessive du liquide cérébro-spinal, que l'une des extrêmités comporte une ouverture (16) qui est essentiellement plus grande que chacune des perforations (18) et que les perforations (18) sont des perforations microscopiques gravées par pulvérisation d'un faisceau ionique.

2. Catheter selon la revendication 1 caractérisé en ce que les pièces microtubulaires (12) sont en fluoropolymère.

3. Catheter selon la revendication 2, caractérisé en ce que les pièces microtubulaires (12) sont constituées par un fluoropolymère sélectionné dans le groupe constitué essentiellement de polytétrafluoroéthylène et de fluoroéthylène-propylène.

4. Catheter selon la revendication 1, comprenant une gaine tubulaire (14) pour renfermer les pièces microtubulaires (12) avec les portions perforées des pièces microtubulaires (12) se prolongeant par une extrêmité de la gaine (14).

5. Catheter selon la revendication 4 caractérisé en ce que la gaine tubulaire 14 est en caoutchouc silicone.

6. Catheter selon la revendication 5 caractérisé en ce que la gaine tubulaire (14) présente un diamètre d'environ 0,015 mètres.

7. Catheter selon la revendication 6, caractérisé en ce que les pièces microtubulaires (12) présentent un diamètre d'environ 0,44 mm.

8. Catheter selon la revendication 7, caractérisé en ce que les perforations (18) des pièces microtubulaires (12) présentent un diamètre d'environ 14 à 150 µ.

9. Procédé de fabrication d'un catheter selon les revendications 1 à 8 caractérisé par:

recouvrement d'un ensemble de pièces microtubulaires (12) avec un cache (28) ayant un ensemble d'ouvertures microscopiques,

disposition des pièces microtubulaires recouvertes (12) dans une installation sous vide, et

exposition du cache (28) à un faisceau ionique, ce qui produit les perforations (18) dans les pièces microtubulaires (12).

10. Procédé de fabrication d'un catheter selon la revendication 9 caractérisé par l'inclusion d'un ensemble de pièces microtubulaires perforées (12) dans une gaine tubulaire (14).

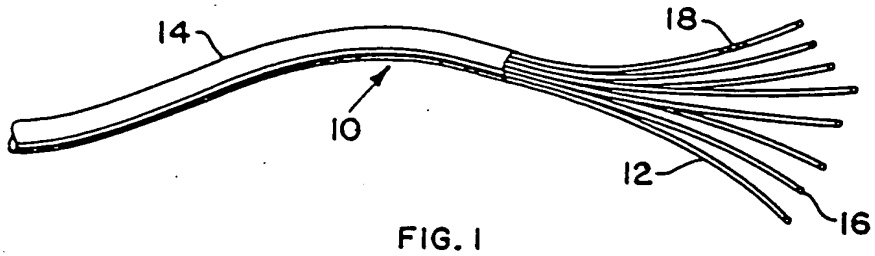

FIG. 1

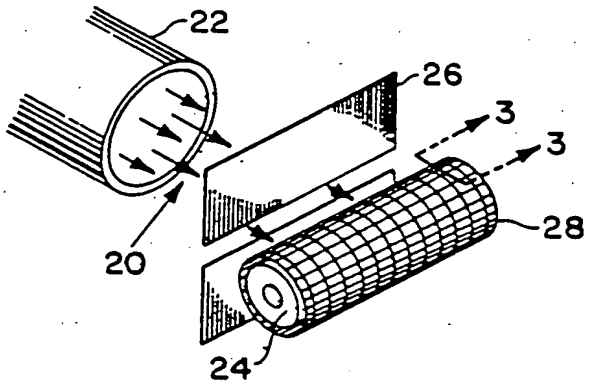

FIG. 2

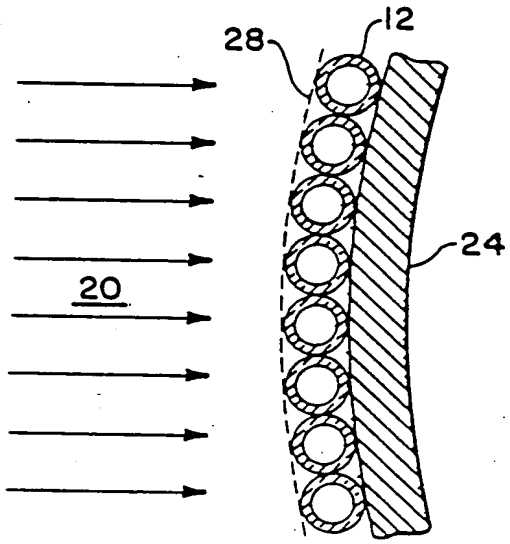

FIG. 3

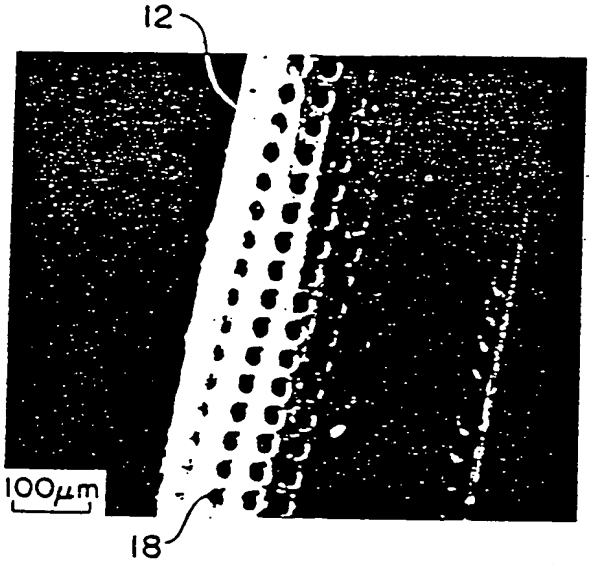

FIG. 4

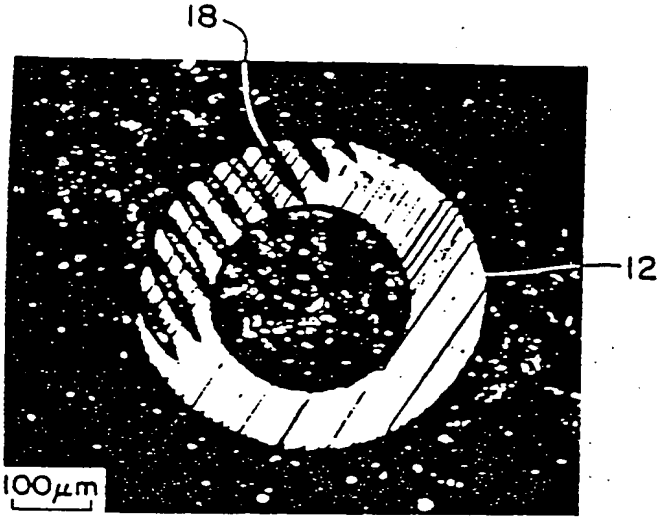

FIG. 5

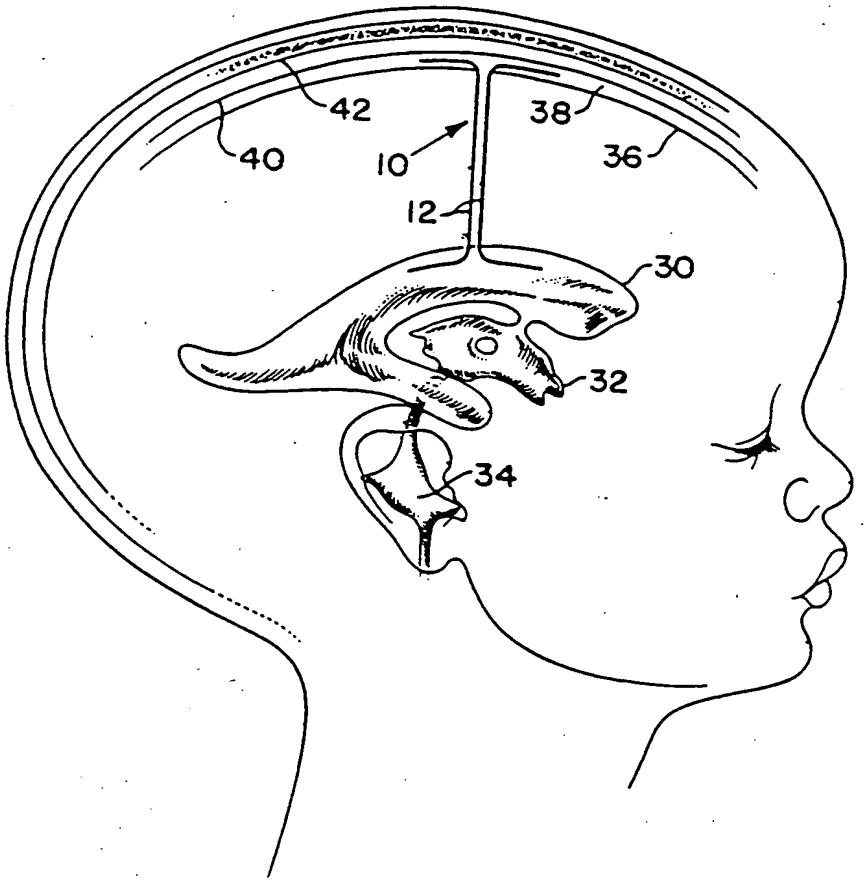

FIG. 6